Expanding Access to HIV/AIDS Treatment

Mission Report India

8-12 December 2003

World Health Organization
Regional Office for South-East Asia
New Delhi

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Contents

Acronyms

ART	Antiretroviral treatment
ARV	Antiretroviral
CII	Confederation of Indian Industries
DOTS	Directly Observed Treatment, Short-course
FICCI	Federation of Indian Chambers of Commerce and Industry
GAVI	Global Alliance on Vaccines and Immunization
IDU	Injecting drug user
MoHFW	Ministry of Health and Family Welfare
NACO	National AIDS Control Organization
NGO	Nongovernmental organization
PLWHA	People living with HIV/AIDS
PMTCT	Prevention of mother-to-child transmission
SACS	State AIDS Control Societies
SEARO	Regional Office for South-East Asia
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
VCT	Voluntary counselling and testing
WRO	WHO Representative's Office

1. Introduction

This report was prepared by a WHO team comprising members from WHO headquarters, the Regional Office for South-East Asia (SEARO), and the WHO Representative's Office (WRO) in collaboration with representatives from UNICEF and UNAIDS. The mission consulted development partners, stakeholders, nongovernmental organizations (NGOs) and civil society representatives. The dialogue on behalf of the Government of India was led by Mr JVR Prasada Rao, Secretary, Department of Health, and Mrs Meenakshi Datta Ghosh, Additional Secretary and Project Director, National AIDS Control Organization (NACO). The mission consulted Mr Ajay Seth, Director, Department of Economic Affairs, Ministry of Finance. The mission is grateful to the officials, partners and colleagues (see Annex 1) who participated or provided support and advice. The programme of the mission is at Annex 2. The WHO team would like to thank the Government of India for its assistance and gracious hospitality.

2. Policy Environment and Political Commitment

On World AIDS Day 2003, the Government of India (GOI) announced a strong policy commitment to provide antiretroviral therapy (ART) to 100 000 people with HIV/AIDS starting 1 April 2004. This policy development is in accordance with the recent declaration of the AIDS treatment gap as a global public health emergency and the launch of the WHO/UNAIDS initiative to provide 3 million people with ART by the end of 2005 ("3 by 5" initiative).

GOI would provide ART in government hospitals in six high-prevalence states, namely, Andhra Pradesh, Karnataka, Maharashtra, Manipur, Nagaland and Tamil Nadu. The main targeted sub-groups are: (a) seropositive mothers who have participated in the prevention of mother-to-child transmission programme (PMTCT); (b) seropositive children less than 15 years, and (c) people living with HIV/AIDS (PLWHA). A working group chaired by the Ministry of Health and Family Welfare (MoHFW) would follow up on this initiative with representation from the Confederation of Indian Industries (CII), Federation of Indian Chambers of Commerce and Industry (FICCI) and manufacturers of antiretrovirals (ARVs). GOI is also pursuing its dialogue with pharmaceutical companies in an effort to further lower domestic prices for ARVs and is reviewing fiscal incentives to bring down prices.

Planning and implementation for the 10-fold increase in overall numbers accessing ART, and perhaps a 100-fold increase in public sector provision of ART, should start now. It cannot be business as usual. The primary

responsibility for meeting the target lies with NACO and the State AIDS Control Societies (SACS). Support however will be forthcoming from WHO, UNAIDS and a wide partnership also committed to rapid expansion of access to AIDS treatment.

Scaling up ART provision in the public sector will help accelerate HIV prevention in India while strengthening health system capacity. All parties recognize that any new activity to scale up ART must be funded through additional resources, without compromising existing prevention, care and mitigation programmes.

3. Current Situation Regarding ART Scale-Up

Currently, the majority of ART delivery in India is through the private sector. Some public sector provision is made through the Central Government Health Scheme, Employees State Insurance services, the Railways and the Department of Defence. Several tertiary-level hospitals are also providing ART, usually at full cost to the individual patient. The NGO sector is providing ART to a limited number of patients often under ad hoc circumstances. There are no accurate data available on the number of patients using these services, the regimens prescribed or the clinical outcome. Although planned, no national ARV monitoring and evaluation system or drug resistance surveillance is yet in place.

India has an unrivalled pool of doctors and other health professionals. Training in HIV care is now part of all medical and nursing curricula, although few students receive adequate practical experience in clinical management. There is limited in-service training in HIV care, largely in the management of opportunistic infections. National guidelines on ART are under development. However, no formal training has been offered on ART, CD4 count and drug resistance measurement. Long-term follow-up of patients on ART is currently inadequate. Relevant linkages between the government and the NGO sector require strengthening.

For rapid scale up, many more patients in immediate need of ART must be identified. Numbers of trained counsellors in place to help rapid scale up are insufficient. Many potential entry points are not providing or offering referral to voluntary counselling and testing (VCT). At directly-observed treatment, short-course (DOTS) tuberculosis (TB) clinics, for example, concerns exist that linkage with VCT may stigmatize TB services. Patients do not access entry points for reasons including lack of knowledge, inadequate services, prohibitive cost of AIDS therapy and discrimination. Patients often end up

in the private sector, which appears to be highly varied in the quality of the clinical services that are on offer. Public-private links are weak.

National and state implementation plans have not yet been developed. The availability of sufficient funding for a 1 April start is an important concern. It is unlikely that mechanisms to raise additional resources from donors for such immediate activities exist.

Systems to procure and supply medicines and diagnostics to treatment centres do not exist. The basic service delivery model(s), including laboratory monitoring, chronic care and long-term adherence in the community are not established. Standard programme indicators for monitoring and evaluation, including ARV resistance surveillance, are not in place.

India has the resources and capacity to scale up ART, and has advantages that many other countries do not have, including established domestic drug manufacturing base and the unrivalled pool of trained health professionals. However, the very rapid scale-up timetable poses unprecedented challenges for programme management and service delivery.

4. Issues Highlighted by the Government

The main issues outlined by the government include the following:

- Mobilization of additional resources through budget supplementation
- Long-term sustainable finance for treatment
- Potential for further GFATM support
- Arrangements for procurement of drugs (perhaps through a consortium or facility)
- Surveillance for drug resistance
- Role and supervision of private sector
- Increased laboratory capacity, including CD4 equipment
- Road map for rapid scale-up.

5. Recommendations

(1) Funding

For rapid scale-up, resources must be identified now for immediate release to issue contracts on drug and equipment purchase, to start training and capacity development for implementing the ART programme starting 1 April 2004 in the six high prevalence states. Ideally, additional health sector funding for this new initiative should be supplementary and extra budgetary.

Rapid mapping of resource requirements and of funds in the pipeline that could be available for 1 April is needed.

(2) Staffing needs

For this ambitious scale-up target, additional staff will be needed to strengthen the managerial and technical base of both NACO and relevant SACS. Given the urgency and the 1 April deadline, and the limited international and national experience in ART delivery on a large scale, such staff expansion may need to encompass international recruitment of individuals with core competency in relevant areas, provided this is done in an accelerated manner.

(3) Planning

Short-term planning is needed to identify and map out critical activities that must be carried out before scale-up is initiated on 1 April or immediately thereafter. Such planning should cover the following areas:

- Designing/implementation of basic ART service delivery model(s) for public sector facilities integrated with the existing structures, particularly at district level.
- Designing/implementation of procurement and supply chain management of drugs and diagnostics.
- Designing/implementation of programme monitoring and evaluation, and resistance surveillance.
- Public-private and NGO linkages.
- Development and implementation of a focused communication strategy.

(4) Capacity and infrastructure development

In accordance with agreed service delivery models, drug supply chain management as well as monitoring and evaluation tools for India, guidelines need to be developed and staff trained immediately. Initial activities should generate both trainers of trainers and the first cadre of implementers and include supportive supervision. Training will need to include community lay workers as well as health professionals. Laboratory infrastructure development will initially involve facilities for CD4 counting and ARV resistance surveillance. Some facilities will need rehabilitation; while in others, new premises to accommodate ART expansion would need to be built.

6. Suggested Action Points

Ten key action points have been identified. The main responsibility for delivery remains with GOI/NACO at national level and with SACS at state level. Support would be provided by WHO, UNICEF, UNAIDS and other

development partners and agencies committed to urgent scaling-up of AIDS treatment.

1. Mobilize additional resources, mainly through extra budgetary supplementation. Additional resources are critical for not compromising preventive programmes. A structured dialogue is to be pursued with donor agencies and the Ministry of Finance.
2. Initiate immediate training of trainers and the first wave of implementers. Training will commence in 11 centres of excellence in the six targeted states.
3. Rapidly deploy national and international staff with core competencies in ART scale-up in the six targeted states and at NACO to further strengthen the capacity of NACO, SACS and the health system.
4. Set up procurement mechanisms for drugs, diagnostics, equipment and supply chain management. An arrangement through a drug facility or consortium will be explored keeping in mind the Global Alliance on Vaccines and Immunization (GAVI) model.
5. Streamline management structures and processes at national and state levels for rapid ART scale-up.
6. Map resources for overall HIV/AIDS programming, including ART, down to district level.
7. Develop a comprehensive road map for ART scale-up with participation from key stakeholders and partners, including the private sector, NGO, PLWHA groups and civil society. This should also include scale-up plans outside the six targeted states.
8. Convene a national meeting to develop consensus on basic delivery model(s) for the public sector and supervised/integrated private and NGO sector ART delivery.
9. Implement a focused communication strategy supporting treatment advocacy, ART awareness and demand generation.
10. Implement monitoring and evaluation programme indicators and surveillance systems for ARV drug resistance in accordance with WHO recommendations. Concurrently, establish an operational research group to facilitate learning by doing and rapid feedback of new knowledge.

ANNEX 1

List of People Met

Government of India

Ministry of Health and Family Welfare

- **Mr J.V.R. Prasada Rao, Secretary,** Department of Health
- **Dr Ashwini Kumar,** Drugs Controller General of India

National AIDS Control Organization

- **Ms Meenakshi Datta Ghosh,** Additional Secretary and Project Director
- **Dr P.L. Joshi,** Additional Project Director
- **Dr Rathore,** Joint Director (Training)
- **Dr Virk,** Consultant PPTCT
- **S.K. Rao,** Director (Finance)

Department of Economic Affairs, Ministry of Finance

- **Mr Ajay Seth,** Director

UNAIDS Theme Group and Partners

- **Dr Maxine Olson,** UN Resident Coordinator and Resident Representative, UNDP
- **Ms Surekha Sabarwal,** UNIASU (United Nations Inter-agency Support Unit)
- **Ms Simran Singh,** UNIASU (United Nations Inter-agency Support Unit)
- **Ms Maria Calivis,** UNICEF Representative
- **Mr Pedro Medrano,** WFP Representative/Country Director
- **Dr David Fletcher,** WFP
- **Ms Caroline Legros,** WFP
- **Ms Renate Ehmer,** UNODC Representative
- **Ms Ena Singh,** UNFPA Representative
- **Dr Francois Farah,** UNFPA
- **Dr Dinesh Agrawal,** UNFPA
- **Ms Sunita Dhar,** UNIFEM
- **Ms Shelly Kaw,** UNIFEM

- **Mr Vishal Dixit,** UNESCO
- **Ms Meera Mishra,** UNDP Regional Programme
- **Ms Nandini Kapoor,** UNAIDS
- **Dr S.N. Misra,** UNAIDS
- **Ms Taslima Lazarus,** UNAIDS ICT
- **Mr Manoj Pardesi,** Indian Network of Positive People, INP+
- **Dr Dora Warren,** Director (CDC), Global AIDS Programme, India
- **Mr Desmond Whyms,** Health Adviser, DFID India
- **Mr Kerry Groves,** First Secretary (Development), AusAID
- **Yasmin Zaveri,** SIDA
- **Ms Asa Anderson,** SIDA
- **Ms Sumita Banerji,** CIDA
- **Mr Sanjay Kapur,** USAID
- **Ms Eileen Stewart,** Canadian High Commission
- **Dr Altaf A. Lal,** Health Attache, US Embassy

Private Sector / Nongovernmental Organizations/Government Hospitals

- **Dr Ashish Sabharwal,** Indian Medical Association
- **Ms Ranu Kulshresth,** Federation of Indian Chambers of Commerce and Industry (FICCI)
- **Dr Sandhya Tewari,** Confederation of Indian Industries (CII)
- **Ms Anjali Gopalan,** Naz Foundation, New Delhi
- **M. Greg Manning,** Sharan, New Delhi
- **Mr Loon Gangte,** Sahara Michael's Care Home, New Delhi
- **Mr Ashok Rau,** Freedom Foundation, Bangalore, Karnataka
- **Mr Ronny Waikhom,** Care Foundation, Imphal, Manipur
- **Mr Jiten Singh,** Continuum of Care Project (COCP), Imphal, Manipur
- **Mr Abraham Kurien,** President, INP+, Chennai, Tamil Nadu
- **Dr A.K. Ganesh,** YRG Care, Chennai, Tamil Nadu
- **Dr Sanjay Pujari,** Ruby General Hospital, Pune, Maharashtra
- **Dr O.C. Abraham,** Christian Medical College (CMC) Vellore, Tamil Nadu
- **Dr S.K. Sharma,** HoD, Department of Medicine, All India Institute of Medical Sciences (AIIMS), New Delhi
- **Dr Ashutosh Biswas,** Department of Medicine, AIIMS, New Delhi

- **Dr Navneet Wig,** Department of Medicine, AIIMS, New Delhi
- **Ms Deepika Khakka,** Department of Medicine, AIIMS, New Delhi

Delhi Society for Promotion of Rational Use of Drugs, National Coordination Meeting

- **Dr Ranjit Roy Chaudhury**
- **Mr R Parameswar**
- **Dr Dinesh Kumar,** Andhra Pradesh
- **Dr R.A. Shaukat,** Bihar
- **Dr Shreeniwas,** Bihar
- **Dr C.L. Kaul,** Chandigarh
- **Dr K. Madangopal,** Chhattisgarh
- **Mr Rattan Chand,** Himachal Pradesh
- **Dr Usha Gupta,** Delhi
- **Dr Uma Thakur,** Delhi
- **Dr Abha Dhalla,** Delhi
- **Dr J.S. Bapna,** Delhi
- **Dr H. Sudarshan,** Karnataka
- **Dr Urmila Thatte,** Maharashtra
- **Dr Basanta K. Mohanty,** Orissa
- **Dr Hardyal Singh,** Punjab
- **Dr P.C. Dandiya,** Rajasthan
- **Dr Rameshwar Sharma,** Rajasthan
- **Dr N.K. Gurbani,** Rajasthan
- **Dr Anita Kotwani,** Rajasthan
- **Dr O.P. Asthana,** Uttar Pradesh
- **Dr M.D. Nair,** Tamil Nadu
- **Dr R Manavalan,** Tamil Nadu
- **Dr Kathleen Holloway**
- **Dr Ruhi Saith**

Other Colleagues

- **Dr Krisantha Weerasurya,** WHO SEARO
- **Dr Sudharshan Kumari,** WHO SEARO
- **Dr S. Salunke,** DGHS Maharashtra, Temporary Advisor to RD

Core Team

- **Dr Salim Habayeb,** WHO India
- **Dr Charles Gilks,** WHO HQ
- **Dr Paramita Sudharto,** WHO India
- **Dr Ying-Ru Lo,** WHO SEARO
- **Mr Binod Mahanty,** WHO India
- **Dr Hendrik V. Hogerzeil,** WHO HQ
- **Mr Alec Irwin,** WHO HQ
- **Dr Jai P. Narain,** WHO SEARO
- **Dr J.P. Wali,** NACO
- **Dr Alka Despande,** J.J. Hospital, Mumbai
- **Dr Kenneth Wind-Andersen,** Country Coordinator UNAIDS
- **Ms Erma Manoncourt,** UNICEF
- **Dr Suvanad Sahu,** WHO India
- **Mr Sunil Nandraj,** WHO India

ANNEX 2

Programme

8 December 2003

08.30 - 10.00 hrs

Briefing of the mission team

- Welcome
- Objectives, outcomes and logistics of the mission
- Announcements

13.00 - 14.00

Central TB Division

- Discussion with senior officials
- Objectives and expected outcomes of the mission
- Briefing on "3 by 5" mission

15.30 - 16.00

UN TG on AIDS in India

16.30 - 17.30

Secretary (Health)

17.30 - 18.00

Wrap-up of Day 1

9 December 2003

09.30 - 14.00 hrs

National AIDS Control Organization

Chair – *Meenakshi Datta Ghosh, Addl. Secretary and Project Director*

- Welcome
- Briefing on care and antiretroviral therapy in India
  Meenakshi Datta Ghosh, Addl. Secretary andProject Director
- "3 by 5" strategy
- Meeting with NACO staff

15.30 - 16.00

Drug Controller (FDA)

18.00 - 18.30

Wrap-up of Day 2

10 December 2003

09.00 - 12.00 hrs

Partners' consultation

- Welcome
- Objectives and expected outcomes of the mission
- Consultation of the role, areas of work as well as short-term and long-term contribution of partners

14.00 - 18.00

Private sector/NGOs/Civil Society consultation

- Welcome
- Objectives and expected outcomes of the mission
- "3 by 5" strategy
- Presentations and sharing of experiences in ART, care and support

11 December 2003 - Field Visits

09.00 - 10.30 hrs

SHARAN
Greg Manning

- Work with IDU

11.00 - 12.30

NAZ FOUNDATION
Anjali Gopalan

- HIV/AIDS care and antiretroviral therapy

14.00 - 16.00

AIIMS
(Dr S.K. Sharma)

- VCT services
- Prevention of parent-to-child transmission services
- HIV clinic/ARV clinic for HIV patients and HIV/TB patients
- EQUAS
- HIV testing facilities
- CD4 count facilities

12 December 2003

09.00 - 14.30 hrs

Wrap-up of the mission

- Report writing
- Preparation of presentations
- Discussion of next steps

11.30 - 12.30

Department of Economic Affairs, Ministry of Finance
Mr. Ajay Seth, Director

15.15 - 16.00

Secretary (Health)
Strategic overview and debriefing on India Mission
WR India and mission team

16.30 - 17.30

UN TG on AIDS in India

18.00 - 20.30

Wrap-up of mission

13 December 2003

10.00 - 11.30

Delhi Society for Promotion of Rational Use of Drugs

- Objectives and expected outcomes of the mission
- "3 by 5" strategy
- Q&A

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